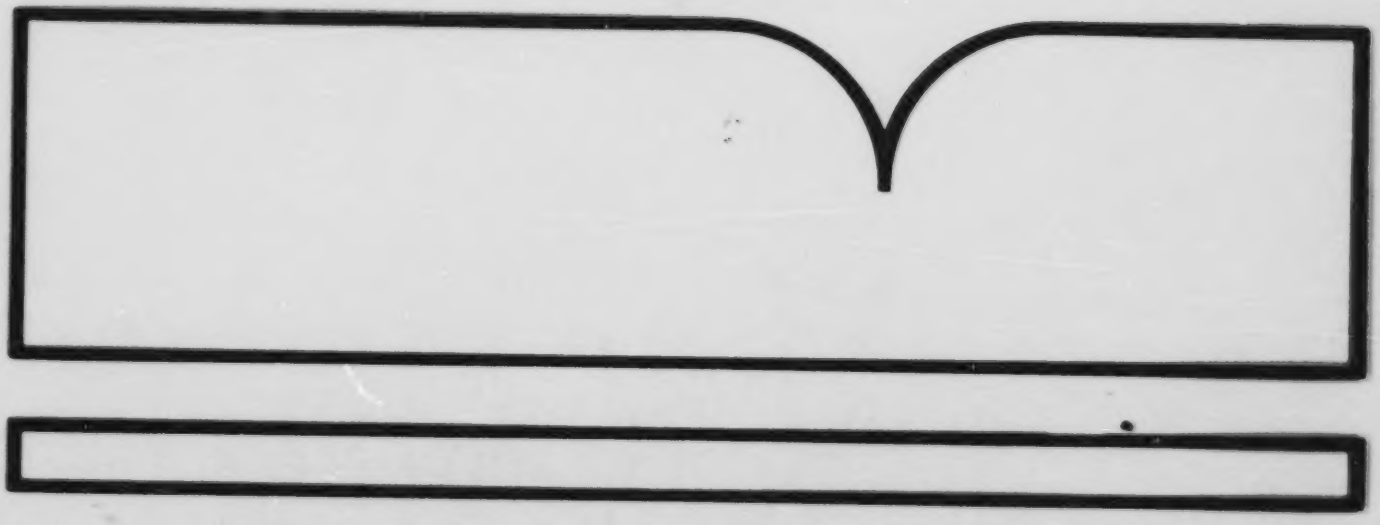
PB89-164214

Guidance for the Reregistration of Pesticide Products Containing Resmethrin as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, Dc

Dec 88



U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE	1. REPORT NO.	2.	3. Recipient's Accession No. PB89 164214/AS
4. Title and Subtitle: Guidance for the Reregistration of Pesticide Products Containing Resmethrin as the Active Ingredient			5. Report Date: December 1988
			6.
7. Author(s): EPA, Office of Pesticide Programs Registration Div.			8. Performing Organization Rept. No. 540/RS-89-032
9. Performing Organization Name and Address: U.S. Environmental Protection Agency, Office of Pesticide Programs, Registration Division TS-767C, 401 M Street, S.W., Washington, D.C. 20460			10. Project/Task/Work Unit No.
			11. Contract(C) or Grant(G) No. (C) (G)
12. Sponsoring Organization Name and Address: Same as #9			13. Type of Report & Period Covered
			14.

15. Supplementary Notes

, The , resmethrin as the

16. Abstract (Limit: 200 words)

This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of date requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manfacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

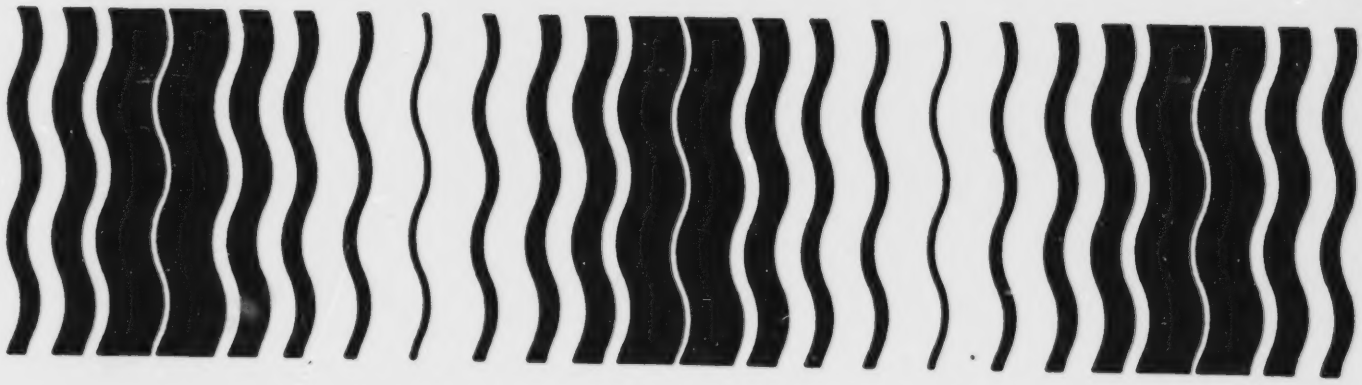
c. COSATI Field/Group

18. Availability Statement: Publicly Available	19. Security Class (This Report): Unclassified	21. No. of Pages: 105
	20. Security Class (This Page): Unclassified	22. Price: A05 PC $21.95 $6.95

Environmental Protection Agency
Pesticides and Toxic Substances
Washington DC 20460
PB89-164214
Pesticides
540/RS-89-032

EPA

Guidance for the Reregistration of Pesticide Products Containing RESMETHRIN as the Active Ingredient



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U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL INFORMATION SERVICE
SPRINGFIELD, VA. 22161

OMB Control No.2070-0057
Expires November 1989

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING RESMETHRIN AS THE ACTIVE INGREDIENT

OPP Chemical No. 097801

GS 0421

CAS (DOCKET) NUMBER: 10453-86-8

December 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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EPA Form 8580-1	FIFRA 3(c)(2)(B) Summary Sheet
EPA Form 8580-3	Generic Data Exemption Statement
EPA Form 8580-4	Product Specific Data Report
EPA Form 8580-6	Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	An acceptable daily intake of pesticide residue based on a complete data base.
a.i.	Active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial or aquatic ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
HDT	Highest dose tested in a toxicity study.
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral : dermal). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LDT	Lowest dose tested in a toxicity study.
LEL	Lowest Effect Level from a toxicity test in animals.
MPI	Maximum Permissible Intake of residues.

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake is an acceptable daily intake of pesticide residue that is based on a limited data base.
ppm	Parts per million
RfD	Reference Dose is an estimate of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The reference dose is a replacement term for the term acceptable daily intake (ADI).
TMRC	Theoretical Maximum Residue Contribution is an estimate of dietary exposure obtained by multiplying residue tolerance levels for a given pesticide by the average daily per capita food consumption figure, then adding the exposure figure for each crop. The TMRC is usually expressed in terms of mg/kg of food.

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request,[1] focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submittal of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

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[1]The scientific reviews and Compendium of Acceptable Uses may be obtained from the OPP Public Docket. Write to OPP Public Docket, Field Operations Division (H7506C), Office of Pesticide Programs, EPA, Washington, D.C. 20460

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submittal of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICALS COVERED BY THIS STANDARD

A. Description of Chemicals

Resmethrin is the American National Standards Institute (ANSI) common name for [5-(phenylmethyl)-3-furanyl] methyl 2,2-dimethyl-3-(2-methyl-1-propenyl) cyclopropanecarboxylate. Resmethrin is composed of 30% cis and 70% trans isomers. The d-trans isomer is also known as bioresmethrin (ISO). Resmethrin is a second generation pyrethroid insecticide that is effective on a broad spectrum of insects. Resmethrin is approximately 20 times more effective than natural pyrethrum in housefly control and may be formulated with a synergist like most pyrethrum products. Resmethrin is more stable than pyrethrum, but decomposes fairly rapidly in sunlight or exposure to air.

Other identifying characteristics and codes are:

Empirical formula: $C_{22}H_{26}O_3$

Molecular weight: 338.4

CAS Registry No.: 10453-86-8

OPP (Shaughnessy) No.: 097801

General Description of Chemical

Resmethrin is a waxy off-white to tan solid synthetic pyrethroid with a chrysanthemate odor. It is insoluble in water, 10% in kerosene, and very soluble in xylene, methylene chloride, isopropyl alcohol and aromatic hydrocarbons.

B. Use Profile

The bulk of resmethrin use is in and around households (indoor and outdoor) and in food handling establishments. Other uses of resmethrin include treatment of ornamentals (outdoor and greenhouse use), commercial/industrial uses, mosquito control, use on pets and horses (non-food use) and insect control in uncultivated nonagricultural areas (i.e. fly control on beaches and at recreational sites).

Resmethrin is primarily formulated into pressurized liquids and ready to use solutions. Refer to Table I. It is also formulated as an emulsifiable concentrate, soluble concentrate, and on impregnated materials. Resmethrin is most frequently formulated with the following pesticides:

D-trans allethrin	155 products
Piperonyl butoxide	79 products
Chlorpyrifos	76 products
Tetramethrin	64 products
Pyrethrins	29 products
Allethrin	19 products

There are about 1200 products which contain resmethrin. Of these 1200 products, only 25 products account for over 70% of the total use of resmethrin.

Table I. Summary Listing of Registered Resmethrin Products

	Registration Status	
	Federal	SLN
Technical	7	
Formulation intermediate	65	
Impregnated materials	2	
Emulsifiable concentrate	114	45
Soluble concentrate	50	44
Ready-to-use solution	392	3
Pressurized liquid	507	4
Totals	1137	57

III. AGENCY ASSESSMENT

The Agency has reviewed all data in the Agency files as of June 13, 1988 supporting the registration of resmethrin. Data received by the Agency after this date have not been reviewed for the purposes of this standard. This section discusses the Agency's scientific findings and conclusions based on these data.

A. Summary

The Agency has reviewed all available data for resmethrin and determined that there are data gaps in the areas of toxicology, residue chemistry, environmental fate, and ecological effects.

A summary of these gaps appears in Table II. Note that this list contains only summary information on the data gaps. More detailed information relating to the issues can be found in the Data Tables in Appendix I.

Table II. SUMMARY OF DATA GAPS FOR RESMETHRIN

Toxicology

Acute Oral
Acute Dermal
Subchronic dermal (21-Day and 90-Day)
Mutagenicity and Genetic Toxicity (full battery of studies including gene mutation, chromosome aberration, and other mechanisms of mutagenicity).
General metabolism and pharmacokinetics

Residue Chemistry

Nature of the residue (metabolism)
- Plants
- Livestock

Residue analytical methods
Storage stability
Magnitude of residue -- Meat/milk/poultry/eggs
Food handling establishments

Environmental Fate

Hydrolysis
Photodegradation
- water

Metabolism studies (Lab)
- aerobic soil
- anaerobic aquatic
- aerobic aquatic

Mobility
- Leaching and adsorption/desorption
- Volatility (Lab)

Dissipation (Field)
- soil
- aquatic (sediment)

Table II. SUMMARY OF DATA GAPS FOR RESMETHRIN - Continued)

Ecological Effects

Avian and Mammalian Testing
- Avian Dietary LC_{50}
- Avian Reproduction

Aquatic Testing
- Fish early life stage
- Freshwater fish LC_{50}
- Acute LC_{50} freshwater invertebrates
- Acute LC_{50} estuarine and marine organisms
- Aquatic invertebrate life cycle

Nontarget Area Phytotoxicity

Tier I
- Seedling germination/seedling emergence
- Vegetation vigor
- Aquatic plant growth

Nontarget Insects
- Honeybee: toxicity of residues on foliage

B. Health Effects Assessment

1. Acute Toxicity

Resmethrin (technical) is moderately or slightly toxic via oral (LD_{50} - 750 to 4500 mg/kg), dermal (LD_{50} - 2500 mg/kg) and inhalation (LC_{50} of > 9.49 mg/l (4 hr. exposure)). It is not considered to be an eye irritant (Toxicity Category IV), a dermal irritant (Toxicity Category IV) or a skin sensitizer in guinea pigs. No neurotoxicity testing is being required since resmethrin is not an organophosphate.

The acute oral toxicity studies and the acute dermal toxicity study have been classified as supplemental or invalid. New studies are required.

2. Subchronic Toxicity

A 90-Day subchronic inhalation study in rats did not demonstrate a definite NOEL. At the lowest dose level tested (0.1 mg/l), there was evidence of behavioral reactions to treatment, decreased blood levels of glucose (in males), decreased body weights and increased serum urea levels (in females). The atmospheric dose levels tested were 0, 0.1, 0.3, and 1.0 mg/l of resmethrin. Subchronic oral toxicity studies are not being required because acceptable chronic studies satisfy this requirement.

Resmethrin was evaluated for its potential to cause neuropathy in rats (axonal swelling and splitting) that is sometimes associated with pyrethroid insecticides. Resmethrin did not induce neuropathy after dietary dose levels that are near fatal (12,640 ppm for seven days) or subchronic dosing (1250 ppm for 32 weeks).

No subchronic dermal (21-Day) data were available for review. A study is required. No 90-Day subchronic dermal data were available for review. A study is required because one of the currently registered uses (Cat and Dog, Animal Treatment - Veterinary Use Only) may result in prolonged and/or repeated exposure to humans.

3. Chronic Toxicity

The Agency has adequate data to characterize the chronic effects of resmethrin.

A rodent (rat) chronic toxicity study did not establish a definite NOEL since there was some evidence of dose related hepatocellular hypertrophy at the lowest dosage level tested (500 ppm or 25 mg/kg/day). This type of response in the liver is regarded as a manifestation of the well recognized phenomenon of hepatic microsomal enzyme system induction which is not regarded as a serious toxicological concern. It is the Agency's opinion that this study does not need to be repeated at a lower dosage. The NOEL in the rat is 500 ppm. At the LEL of 2500 ppm increased liver weight and severe pathological lesions in this organ were observed. Further dose related increases in liver weight, liver pathology, and also increases in thyroid weight and incidence of thyroid cysts were observed at the 5000 ppm (HDT) level.

A dog chronic study demonstrated a NOEL of 10 mg/kg/day and a LEL of 30 mg/kg/day. At the 30, 100 and 300 mg/kg/day levels there were dose related increases in liver weight.

4. Oncogenicity

Resmethrin was determined not to be oncogenic for rats at dosage levels up to and including 5000 ppm (HDT). The dose levels tested on rats were 0 ppm, 500 ppm (25mg/kg/day), 2500 ppm (125 mg/kg/day) and 5000 ppm (250 mg/kg/day). Additional historical control information has been requested with respect to the thyroid gland. Resmethrin does not produce oncogenic effects in mice at dosage levels up to and including 1000 ppm (HDT) when administered in the diet for 18 months. The dose levels tested on mice were 0 ppm, 250 ppm (37.5 mg/kg/day), 500 ppm (75 mg/kg/day), and 1000 ppm (150 mg/kg/day).

5. Developmental Toxicity and Teratogenicity

Two acceptable teratogenicity studies for resmethrin are available. Doses tested were: 0, 20, 40, and 80 mg/kg/day. The teratogenic NOEL for rats was 40 mg/kg/day based on slight increase in aberrations in skeletal findings. There was an indefinite maternal NOEL with some decrease in food consumptions at all dose levels tested and a body weight decrease at the 80 mg/kg/day level.

The doses tested in rabbits were 0, 10, 30, and 100 mg/kg/day. The teratogenic, maternal and fetotoxic NOELs in the rabbit were greater than 100 mg/kg/day (HDT).

6. Reproduction

The Agency has an acceptable multigeneration reproduction study in the rat. A definite NOEL was not established in this study since there were marginally statistically significant increases in the number of pups born dead and decreases in pup weight at weaning at the lowest dosage level tested (500 ppm or 25 mg/kg/day). The observed effects were judged to be minimal when the low dose groups were compared with the controls. An additional multigeneration reproduction study is not required.

7. Mutagenicity

No acceptable mutagenicity and genetic toxicity data are available. A gene mutation study was determined to be unacceptable in satisfying the data requirements. A full battery of studies including a new gene mutation study, chromosomal aberration and other mechanisms of mutagenicity are required.

8. General Metabolism

There are no general metabolism studies available to the Agency. A study in the rat is required.

9. Human Exposure (or Reentry)

Based on the toxicological profile of resmethrin (low acute toxicity, non-oncogenic, minimal reproductive and fetotoxic effects), data on human exposure and reentry are not required.

C. Environmental Characteristics and Effects

1. Environmental Fate

No acceptable or supplemental data on resmethrin are available to assess the environmental fate and transport, and potential exposure of humans and nontarget organisms. The potential for resmethrin to contaminate groundwater is unknown. However, based on the non-leaching characteristics of related pyrethroid compounds and the fact that more than half of the 130,000 lbs. of resmethrin used annually is used indoors, it is not likely that use of this chemical will pose appreciable risks to groundwater. Also, in a Mobility - Column Leaching Study, while unacceptable in meeting current EPA Guidelines, [^{14}C]resmethrin exhibited virtually no leaching.

The following data are needed to fully assess the environmental fate and transport of resmethrin for its current uses: hydrolysis, photodegradation in water, aerobic and anaerobic aquatic and soil metabolism, leaching/adsorption-desorption, terrestrial and aquatic field dissipation, and fish accumulation studies.

2. Ecological Effects

There is sufficient data to assess the acute oral toxicity of resmethrin in birds (LD_{50} >2000 mg/kg - California quail) as slightly toxic.

Resmethrin is very highly toxic to bluegill sunfish, LC_{50} values range from 0.75 to 2.6 ug/L, and rainbow trout with LC_{50} values ranging from 0.28 to 2.4 ug/L. The most sensitive aquatic organism is the rainbow trout, with an LC_{50} of 0.28 ppb. The bluegill LC_{50} is 0.75 ppb.

Direct application to water is the worst case scenario for the exposure of aquatic species. This case is likely to occur with the labeled use of Resmethrin in mosquito control, because listed sites include: shorelines, beaches, tidal marshes, marsh lands, marshy areas, stagnant pools, and swamps which consist of shallow water habitats. As indicated below, direct application to water can be expected to have an adverse impact on aquatic organisms.

Resmethrin Impact on Aquatic Organisms

Application	Label Rate	EEC[1/]	EEC Exceedance of the LC_{50} for Trout and bluegill[2/]
Mosquito	0.007 lb/Acre	5.1 ppb	18x and 7x
Mosquito	0.001 lb/Acre	0.73 ppb	2.6x and 1x
Stable flies (at beaches in FL)	0.017 lb/Acre	14 ppb	50x and 19x
Chrysops deer flies	0.05 lb/Acre	36.7 ppb	131x and 49X

1. Expected environmental concentration for a one acre pond 6 inches deep.

2. LC_{50} for Rainbow trout = .28 ppb and LC_{50} for bluegill = .75 ppb.

The following data were not available to assess the ecological effects of resmethrin. These studies are required:

Avian dietary toxicity
Avian reproduction
Effects on freshwater invertebrates
Effects on estuarine and marine organisms
Fish early life stage
Aquatic plant testing
Degradate toxicity
Persistence testing

A complete hazard assessment for aquatic invertebrates, marine/estuarine species or nontarget plants cannot be completed until the outstanding data requirements are satisfied.

Beneficial Insects

Resmethrin is highly toxic to honey bees in a laboratory acute contact study (LD_{50} - 0.063 ug/bee). No data were available on the toxicity of foliar residues. These studies are required.

Endangered Species

The uses of resmethrin do not present a potential hazard to endangered birds or mammals on an acute basis. However, resmethrin does present a potential hazard to endangered fish on an acute basis.

Because of the toxicity of resmethrin, and the potential for exposure, resmethrin has the potential to adversely effect endangered species. Resmethrin was included in a previous Consultation submitted to the U.S. Fish and Wildlife Service for endangered species hazard assessment. However, the endangered species hazard assessment cannot be completed without additional information concerning the effects of resmethrin on bird reproduction, fish early life stage, aquatic invertebrate, marine/estuarine species, and phytotoxicity. When available, EPA will submit any additional data concerning levels of resmethrin that may affect these species to the U.S Fish and Wildlife Service. If a jeopardy opinion is returned by FWS, appropriate action will be taken by EPA to limit the use of resmethrin to protect jeopardized species.

d. Tolerance Reassessment

Residue Chemistry

No tolerances have been established for residues of resmethrin in or on any plant or animal commodities. A food additive tolerance of 3ppm (40 CFR 185.5300) has been established for residues of resmethrin in food items resulting from treatment of food handling establishments and storage areas.

No Codex MRLs have been established for residues of resmethrin in or on food or feed.

Nature of the Residue in Plants

Presently no tolerances or exemptions from the requirement of tolerances exist for residues of resmethrin in or on plant commodities. Data on the metabolism of resmethrin in tomatoes, lettuce, and wheat were submitted in support of proposed uses on cucumbers and tomatoes. These data were determined to be inadequate. These studies will be required if products are intended for use on agricultural food or feed crops.

Nature of the Residue in Animals

No tolerances or exemptions from the requirement of tolerances for resmethrin residues in animal commodities have been established. The metabolism of resmethrin in milk has been adequately described; virtually all of the ^{14}C-labeled resmethrin present in milk was identified as unchanged parent material.

However the metabolism of resmethrin in animal tissues was not adequately understood because the studies reviewed did not identify the total terminal residues in meat, fat, liver and kidney. No poultry metabolism data were available for review. Data depicting the nature of residue in ruminants and poultry must be submitted to support the use of resmethrin in food handling establishments.

Residue analytical Methods

Adequate gas-liquid chromatographic/flame ionization detection (GLC/FID) methods are available for collection of data pertaining to residues of resmethrin per se in or on food products and inanimate surfaces. Data for PAM I Multiresidue Protocols I, II and III are required for resmethrin and any metabolites of concern.

Tolerance Assessment - ADI Assessment

The RfD is 0.03 mg/kg/day. This RfD determination is based on the rat multi-generation reproduction study which demonstrated minimal effects at the lowest dosage level tested (500 ppm, 25 mg/kg/day). The LEL dosage level used for this study was used together with uncertainty factors of 100 to account for the inter- and intra- species differences in toxicity and an additional 10 to account for the lack of a definite NOEL for the study.

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Positions and Rationale

Based on the review and evaluation of all available data on resmethrin, the Agency has made the following determinations. Where label revisions are specified, language is set forth in Section B of this Chapter.

1. The Agency is not placing resmethrin into Special Review at this time. EPA has insufficient information to determine that the criteria of 40 CFR 154.7 for special review are met. The Agency will further evaluate the potential risk to aquatic species when data required under the Standard are submitted.

Rationale: The Agency has significant concerns about the toxicity of resmethrin to aquatic species. Resmethrin is highly toxic to fish, and, based on its structural similarity to other pyrethroid compounds, may also be highly toxic to aquatic invertebrate species. The Agency is requiring additional data on aquatic invertebrate toxicity and the fate of resmethrin in the environment.

Theoretical calculations of exposure to aquatic species based upon maximum application rates suggest that resmethrin may pose a hazard to aquatic species from its agricultural and mosquito uses. All calculated EECs for runoff from agricultural use and direct application to aquatic sites for mosquito control were above the LC_{50} for both bluegill sunfish and rainbow trout. Even the lowest application rate for mosquito application theoretically equals or exceeds the LC_{50} for fish.

2. The Agency is imposing restricted use classification for certain outdoor uses of resmethrin, based upon its toxicity to fish.

Rationale: Resmethrin meets the criteria for restricted use based on acute fish toxicity. All products with outdoor use patterns for mosquito abatement and insect control at uncultivated nonagricultural sites (i.e. beaches, parks, campsites woodlands, atheletic fields, golf courses, swamps, tidal marshes, refuse and waste sites, residential areas and municipalities) are classified as Restricted Use because of their high toxicity to fish. These products will be required to bear appropriate labeling.

3. The Agency is not requiring the use of protective clothing or establishment of reentry intervals for resmethrin.

Rationale: Based on available toxicological information, there are no concerns with human exposure which will require personal protective clothing and specific field reentry intervals.

4. The Agency is not requiring the addition of a groundwater advisory statement to resmethrin labels.

Rationale: Although the potential for resmethrin to contaminate groundwater is unknown, it is not likely that the use of this chemical will pose an appreciable risk to groundwater because:

A. Almost half of the 130,000 lbs. of resmethrin produced annually is used indoors.

B. Other structurally similar pyrethroid compounds do not leach.

Also, the mobility data reviewed, while unacceptable in meeting current EPA Guidelines, indicated that that resmethrin does not leach and remains near the soil surface.

5. The available residue chemistry data are insufficient to permit the Agency to conduct a full tolerance reassessment. However, the toxicology data base is relatively complete. The Agency will grant tolerances for food uses if adequate residue data are submitted to support the tolerance request.

Rationale: Data gaps exist depicting the nature of residue in representative food products resulting from the contamination of resmethrin treatments in food handling and storage areas; the nature of residue (metabolism) in plants and livestock; analytical residue methods; and storage stability.

6. The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain of the data being required by the Agency are essential to resolve risk concerns, or may generate the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

158.150 Wildlife and Aquatic Organisms

- These studies will permit the Agency to determine whether resmethrin exceeds the risk criterion for special review.

158.290 Environmental Fate

- These studies are tiered studies that may require the generation of additional studies and will be used to determine whether resmethrin exceeds the risk criteria for special review.

8. Continuation of registration. While data gaps are being filled, currently registered manufacturing use products (MPs) and end use products (EPs) containing resmethrin may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7).

Issuance of this Standard provides a mechanism for identifying data needs and labeling changes arising from available data. Required data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain resmethrin, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain this pesticide. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing this pesticide provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the use patterns listed below. The EPA Compendium of Acceptable Uses (for availability, see page 1) lists all registered uses, as well as approved maximum application rates and frequencies.

Domestic: Indoor Household

This use pattern includes applications to control insects in indoor areas of single family homes,mobile homes, townhouses, condominiums and apartments.

Domestic:Outdoor Household

This use pattern includes applications to all exterior portions of the house including foundations, door and window frames, screens, eaves, porches, patios, garage areas, outdoor sheds, etc. This use pattern also includes treatment of the yards surrounding the dwelling for household pests. This use pattern specifically excludes all treatments to structures against standard pest such as termites and to yards for pests whose only damage is to the vegetation (e.g. sod webworms, gypsy moths).

Indoor Food Handling Establishments (Edible product areas)

This use pattern includes food processing plants, eating establishments (e.g. restaurants), supermarkets, and food warehouses. An edible product area of food handling establishments include areas for receiving, serving, storage, preparing and processing.

Greenhouse ornamental

This use pattern includes application to ornamental plants in commercial and retail greenhouses. It does not include use on food crops grown in greenhouses.

Mosquito Control

This use pattern includes application to specific sites for the control of mosquitos, flies, and midges. Resmethrin may be applied under this use pattern to the following sites: parks, campsites, woodlands, athletic fields, golf courses, swamps, tidal marshes, refuse and waste sites, residential areas and municipalities. It may not be applied to agricultural sites.

Animal Treatment

This use pattern includes applications to animal premises (i.e., barns, stables, kennels) and direct applications to livestok (non-food) and pets for control of fleas, flies and ticks.

D. LABELING

In order to remain in compliance with FIFRA, products must bear appropriate labeling as specified in 40 CFR 156.10 and this Standard, or must be revised to conform to those specifications. Appendix II contains information on label requirements.

No pesticide product containing this pesticide may be released for shipment by the registrant after December 31, 1989, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing this pesticide may be distributed or sold after December 31, 1990 unless the product bears an amended label which complies with the requirements of this Standard.

The following specific information must appear on the labeling in order for products to remain in compliance with FIFRA:

1. Ingredients Statement

The ingredient statement for products must list the active ingredient as:

ACTIVE INGREDIENT

Resmethrin.....____ %

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in the EPA Compendium of Acceptable Uses. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

3. Precautionary Statements

Manufacturing Use Product:

"This pesticide is highly toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public water unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."

Outdoor Use

1. Mosquito abatement and pest control treatments at nonagricultural sites.

"This pesticide is highly toxic to fish. Drift and runoff from treated sites may be hazardous to fish in adjacent waters. Consult your State's Fish and Wildlife agency before treating such waters."

2. Other than mosquito abatement or pest control treatments at nonagricultuaral sites.

"This pesticide is highly toxic to fish. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Drift and runoff from treated sites may be hazardous to fish in adjacent waters. Do not contaminate water when disposing of equipment washwaters."

4. Restricted Use:

All products labeled for mosquito abatement and pest control treatments at nonagricultural sites (i.e. beaches, parks, campsites, woodlands, athletic fields, golf courses, swamps, tidal marshes, refuse and waste sites, and municipalities) are classified RESTRICTED USE and must bear the following restricted-use classification:

"RESTRICTED USE CLASSIFICATION
Due to acute fish toxicity

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B.[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2]Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption,[3] the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

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[3]If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

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[4]Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submitted by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

[Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6. (cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: Resmethrin Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

TGUIDE-1

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Prot Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F= Greenhouse. non-food

G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data
requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column t requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE TECHNICAL GRADE OF THE ACTIVE INGREDIENT: RESMETHRIN[1].

Data Requirement	Test Substance[2]	Does EPA have data to satisfy this requirement?[3]	Bibliographic Citation[3]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
158.190 Product Chemistry					
Product Identity and Composition					
61-2. Description of Beginning Materials and Manufacturing Process	TGAI	No	N/A	Yes[4]	9 months
61-3. Discussion of Formation of Impurities	TGAI	No	N/A	Yes[5]	9 months
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis of Product Samples	TGAI	No	N/A	Yes[6]	12 months
Physical and Chemical Characteristics					
63-2. Color	TGAI	No	N/A	Yes[7]	9 months
63-3. Physical State	TGAI	No	N/A	Yes[7]	9 months
63-4. Odor	TGAI	No	N/A	Yes[7]	9 months
63-5. Melting Point	TGAI	No	N/A	Yes[7,8]	9 months
63-6. Boiling Point	TGAI	No	N/A	Yes[7,9]	9 months
63-7. Density, Bulk Density or Specific Gravity	TGAI	No	N/A	Yes[7]	9 months
63-8. Solubility	TGAI or PAI	No	N/A	Yes[7]	9 months
63-9. Vapor Pressure	TGAI or PAI	No	N/A	Yes[7]	9 months
63-10. Dissociation Constant	TGAI or PAI	No	N/A	Yes[7]	9 months
63-11. Octanol/Water Partitioning Coefficient	PAI	No	N/A	Yes[7]	9 months
63-12. pH	TGAI	No	N/A	Yes[7,10]	9 months
63-13. Stability	TGAI	No	N/A	Yes[7]	9 months
Other Requirements:					
64-1. Submittal of Samples	N/A	N/A	N/A	No	

(Continued, footnotes follow).

TABLE A. (Continued).

1. All currently registered technical products are also manufacturing-use products; therefore, additional data requirements pertaining to these products are listed in Table B.

2. TGAI = technical grade of the active ingredient. PAI = purified active ingredient.

3. Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

4. Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

5. A detailed discussion of all impurities that are or may be present at $\geq$0.1%, including nitrosamines, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

6. Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete, detailed descriptions of the analytical methods used must be submitted along with statements of their precision and accuracy. Reports of preliminary analyses should include for each sample the identity of each ingredient for which analysis was conducted, the quantity that was found, and the mean and relative standard deviation of reported analytical results.

7. Data must be submitted on physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D. See Table B for additional requirements for data on physicochemical characteristics of technical products that are also manufacturing-use products.

TABLE A. (Continued).

Guidelines, Subdivision D. See Table B for additional requirements for data on physicochemical characteristics of technical products that are also manufacturing-use products.

8. Data on melting point are required if the technical chemical is a solid at room temperature.

9. Data on boiling point are required if the technical product is a liquid at room temperature.

10. Data on pH are required if the test substance can be diluted or dispersed in water.

TABLE A. GENERIC DATA REQUIREMENTS FOR RESMETHRIN.

Data Requirement		Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission[1]
158.240 Residue Chemistry						
171-2.	Chemical Identity[2]					
171-3.	Directions for use		(See Index)			
171-4.	Nature of the residue (Metabolism) - Plants	PAIRA	Partially	00128626.	Yes[3]	18 months
171-4.	Nature of the residue (Metabolism) - Livestock	PAIRA and plant metabolites	Partially	00159388.	Yes[4,5]	18 months
171-4.	Residue analytical methods	TGAI and metabolites	Partially	00077182. 00123575. 00129282.	Yes[6,7]	15 months
171-4.	Storage stability	TEP and metabolites	No	N/A.	Yes[8]	15 months
171-4.	Magnitude of residue in Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	No	N/A.	Reserved[9]	18 months
171-4.	Food Handling Establishments	PAIRA and/or plant metabolites	Partially	00123575. 00129282.	Yes[10,11]	12 months

1. Data must be submitted within the indicated time frame, based on the date of this Guidance Document.

TABLE A. Footnotes (Continued).

2. The same chemical identity data are required as under 158.150-158.190, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

3. The Agency has assumed that the metabolism/degradation of a pesticide in food handling establishments will result in metabolites similar to those in growing plants. The requirements for degradation studies to support the established food additive tolerance for residues resulting from treatment of food handling establishments are detailed in footnote 11.

4. Metabolism studies utilizing ruminants and poultry. Animals must be dosed orally for a minimum of 3 days with 2-furan-labeled [^{14}C]resmethrin and carboxy-labeled [^{14}C]resmethrin, in separate tests, at levels sufficient to make residue identification and quantification possible. Eggs must be collected twice a day during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and identity of residues must be determined in eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using proposed enforcement methods to ascertain that the methods are capable of adequately recovering and identifying all residues of toxicological concern.

5. Data depicting the nature of resmethrin residues in swine are also required if the required metabolism studies with ruminants and poultry reveal that the metabolism of resmethrin in these animals differs from that in rats.

6. Representative food samples bearing residues of resmethrin must be analyzed by multiresidue protocols I, II, III which are available from the National Technical Information Service under Order No. PB 203734/AS.

7. The results of a successful confirmatory trial of the Penick Corp. GLC method designated no. 1047 (revised), conducted by an independent laboratory, must be submitted for representative food samples. Results of at least one set of samples per commodity (a total of six samples, including two control samples, two control samples fortified at the tolerance level, and two control samples fortified at 2-5 times the tolerance level) must be submitted. No more than three sets of samples per commodity may be tested to achieve successful recovery rates of 70-120% with negligible interference compared to the established tolerance(s). For additional details of data requirements, refer to PR Notice 88-5, Tolerance Enforcement Methods - Independent Laboratory Confirmation by Petitioner.

8. Storage intervals and conditions must be supplied for all required and previously submitted data for food product samples. This information must be accompanied by data depicting the percent decline in residues of resmethrin under the storage conditions and for the intervals specified. Fortified samples of representative food commodities must be analyzed immediately after fortification and again after storage

TABLE A. Footnotes (Continued).

intervals that are equivalent to those reflected in all previously submitted and currently requested data. The chosen intervals must allow for unforseen delays in sample storage. For additional guidance on conducting storage stability studies, the Registrant is referred to an August 1987 Position Document on the Effects of Storage on Validity of Pesticide Residue Data available from NTIS under order no. PB88112362/AS.

9. Following receipt and evaluation of the required plant metabolism/degradation and animal metabolism data, storage stability data, and residue data for feed items, specific data requirements for livestock feeding studies will be determined.

10. Data depicting the nature of the residue in representative food products from typical food handling establishments resulting from known contamination by [^{14}C]resmethrin. Tests conducted must represent the range of normal heating and processing procedures following fortification with the [^{14}C]resmethrin at typical stages where contamination resulting from treatment of the establishment premises might occur. Characterization of residues must be conducted in samples representing the range of normal shelf life for the food products. Alternatively, adequate characterization of residues in plant metabolism studies may be conducted. Should the studies of the nature of the residue reveal the presence of degradation products of concern other than resmethrin per se, analysis for such residues must also be included in residue tests.

11. Data depicting the magnitude of residues of concern in food products resulting from the application of normal and exaggerated rates of representative SC/L and EC formulations of resmethrin in food service, food manufacturing, and food processing establishments (two representative types of each food handling establishment as listed in Table 1 of Subdivision O of the Pesticide Assessment Guidelines). Conducted tests must be representative examples of worst-case scenarios for potential residue contamination of food products which might include, but are not limited to, some of the following: (i) particulate aerosol contact with packaged products or unwrapped fresh produce present and/or on display at the time of resmethrin treatment; (ii) contact of packaged foods with treated surfaces, such as flour sacks stacked on treated floor surfaces in storage areas; (iii) accidental treatment of food work surfaces and subsequent contact of food before surfaces are cleaned; (iv) treatment occurring near stacks of new or cleaned product containers that are filled without being cleaned; and (v) distribution of residues in continuous process food operations from treatment of ends and tailings, conveyor lines, boots, etc., when operation is shut down. Exposure situations in grocery stores and restaurants must include a representative range of foods such as oily foods, baked cereal products, raw and cooked meats, and fresh fruits and vegetables.

Table A
Generic Data Requirements for Resmethrin

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Sec. 158.290 Environmental Fate						
Degradation Studies - Lab						
161-1 - Hydrolysis	TGAI or PAIRA	B,D,E, F,H,I	No		Yes	9 months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	B,D	No		Yes	9 months
161-3 - On Soil	TGAI or PAIRA	-	No		No	
161-4 - In Air	TGAI or PAIRA	-	No		No	
Metabolism Studies - Lab						
162-1 - Aerobic Soil	TGAI or PAIRA	B,E,F	No		Yes	27 months
162-2 - Anaerobic Soil	TGAI or PAIRA	-	No		No	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	D	No		Yes[1/]	27 months
162-4 - Aerobic Aquatic	TGAI or PAIRA	D	No		Yes[1/]	27 months
Mobility Studies						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	B,D,E,F,H	No		Yes	12 months

Table A
Generic Data Requirements for Resmethrin (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission[1/]
Sec. 158.290 Environmental Fate (cont'd)						
163-3 - Volatility (Field)	TEP	E,F	No		No[2/]	
Dissipation Studies - Field						
164-1 - Soil	TEP	B,H	No		Yes	27 months
164-2 - Aquatic (Sediment)	TEP	D	No		Yes[1/]	27 months
164-3 - Forestry	TEP	-	No		No	
164-4 - Combination and Tank Mixes	TEP	-	No		No[3/]	
164-5 - Soil, Long-Term	TEP	-	No		Reserved[4/]	
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	-	No		No	
165-2 - Rotational Crops (Field)	TEP	-	No		No	
165-3 - Irrigated Crops	TEP	-	No		No	
165-4 - In Fish	TGAI or PAIRA	B,D	No		Yes	12 months

Table A
Generic Data Requirements for Resmethrin (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Sec. 158.390 Reentry Protection						
132-1 - Foliar Dissipation	TGAI	-	No		No[6/]	
132-1 - Soil Dissipation	TGAI	-	No		No[6/]	
133-3 - Dermal Exposure	TGAI	-	No		No[6/]	
133-4 - Inhalation	TGAI	-	No		No[6/]	
Sec. 158.440 Spray Drift						
202-1 Drift Field Evaluation	TGAI	B	No		Reserved[7/]	
202-1 Drift Size Spectrum	TGAI	B	No		Reserved[7/]	

Table A

Generic Data Requirements for Resmethrin (cont'd)

Sec. 158.290 Environmental Fate
Footnotes

1/ The aquatic data requirement is being imposed for the use of resmethrin on beaches, marsh lands, etc.

2/ Resmethrin does not have a terrestrial food use to require field volatility data.

3/ This requirement is not being imposed at the present time.

4/ This data requirement is deferred pending evaluation of the aerobic soil metabolism, leaching and dissipation data.

5/ This data requirement is reserved pending the evaluation of the fish accumulation study.

6/ Available toxicological data do not trigger human exposure concerns under present Guidelines.

7/ Spray drift data requirements are reserved pending evaluation of the outstanding invertebrate toxicity data.

Table A
Generic Data Requirements for Resmethrin

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.340 Toxicology						
81-1 - Acute Oral - Rat	TGAI	All	No	00123346 00123347 00123490	Yes	9 months
81-2 - Acute Dermal	TGAI	All	No	00133890	Yes	9 months
81-3 - Acute Inhalation	TGAI	All	Yes	00158477	No	
81-4 - Eye Irritation	TGAI	All	Yes	00028466	No	
81-5 - Dermal Irritation	TGAI	All	Yes	00028466	No	
81-6 - Dermal Sensitization	TGAI	All	Yes	00158478	No	
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI		No		No[1/]	
Subchronic Testing						
82-1 - 90-Day Feeding -						
Rodent	TGAI	A,E	No		No[2/]	
Non-rodent	TGAI	A,E	No		No[2/]	

Table A
Generic Data Requirements for Resmethrin (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.340 Toxicology						
Subchronic Testing (cont'd)						
82-2 - 21-Day Dermal	TGAI	All	No		Yes	12 months
82-3 - 90-Day Dermal	TGAI		No		Yes[3]	15 months
82-4 - 90-Day Inhalation - Rat	TGAI	E,F,I	Yes	00158476	No	
82-5 - 90-Day Neurotoxicity - Rat	TGAI		Yes	00025552, 00025553, 00025554	No	
Chronic Testing						
83-1 - Chronic Testing -Rodent	TGAI	A,E	Yes	00085870, 00108828 00147770, 00147771, 00158495	No	
-Dog	TGAI	A,E	Yes	00157961	No	
83-2 - Oncogenicity -Rat	TGAI	A,E	Yes	00085870, 00108828, 00147770, 00147771, 00158495	No[4]	
-Mouse	TGAI	A,E	Yes	00083319	No	
83-3 -Teratogenicity -Rat	TGAI	All	Yes	00028453	No	
-Rabbit	TGAI					

Table A
Generic Data Requirements for Resmethrin (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.340 Toxicology						
Chronic Testing (cont'd)						
83-4 - Reproduction - Rat	TGAI	A,E	Yes	00081276, 00124308 00124122, 00107885	No	
Mutagenicity Testing						
84-2 - Gene Mutation	TGAI	All	No	00057853	Yes	9 months
84-2 - Chromosome Aberration	TGAI	All	No		Yes	12 months
84-4 - Other Mechanisms of Mutagenicity	TGAI	A,B	No		Yes	12 months
Special Testing						
85-1 - General Metabolism	PAI or PAIRA	A,E	No		Yes	24 months

1/ Since resmethrin is not an organophosphate, this study is not required.
2/ The availability of acceptable chronic feeding studies in rats and dogs eliminates the need to require these subchronic feeding studies.
3/ 90-Day subchronic dermal studies are required because veterinary use products may result in daily exposure to humans (i.e. Animal care technicians who dip and/or shampoo animals).
4/ Additional information regarding historical control data for spontaneous development of thyroid tumors has been requested of the registrant as of May 1988.

Table A
Generic Data Requirements for Resmethrin

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Sec. 158.490 -Wildlife and Aquatic Organisms						
Avian and Mammalian Testing						
71-1 -Avian Acute Oral Toxicity						
- Upland game bird	TGAI	B,D,G	Yes	00160000	No	
71-2 - Avian Dietary LC_{50}						
- Upland Game Bird	TGAI	B,D,[F,I][1]G	No		Yes[2]	9 months
- Waterfowl	TGAI	B,D,[F,I][1]G	No		Yes[2]	9 months
71-3 - Wild Mammal Toxicity	TGAI	B,D,G	Yes		No[3]	
71-4 - Avian Reproduction	TGAI	B,D,G	No		Yes[4]	24 months
71-5 - Actual Field Testing for Birds and Mammals	TEP	B,D,G	No		No[5]	

Table A
Generic Data Requirements for Resmethrin (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Sec. 158.490 -Wildlife and Aquatic Organisms						
Aquatic Organism Testing						
72-1 - Freshwater Fish LC_{50}						
- Warmwater	TGAI	B,D,[F,I][1]/G	Yes	40098001	No	
	TEP	B,D,G	No		Yes[6]/	9 months
- Coldwater	TGAI	B,D,[F,I][1]/G	Yes	40098001	No	
	TEP	B,D,G	No		Yes[6]/	9 months
72-2 - Freshwater						
Invertebrate LC_{50}	TGAI	B,D,[F,I][1]/G	No		Yes [2]/	9 months
	TEP	B,D	No		Yes[6/7]/	9 months
72-3 - Estuarine and Marine	TGAI	B,D,G	No		Yes[8]/	9 months
Organisms LC_{50}	TEP	B	No		Yes[9]/	9 months
72-4 - Fish Early Life Stage and Invertebrate Life Cycle						
- Freshwater Fish Invertebrates	TGAI	B,D,G	No		Yes	15 months

Table A
Generic Data Requirements for Resmethrin (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Sec. 158.490 -Wildlife and Aquatic Organisms						
-marine/estuarine Fish Invertebrates	TGAI	B,D,G	No		Reserved[10/]	
72-5 Fish Life Cycle	TGAI	B,D,G	No		No[5/]	
72-6 Aquatic Organism Accumulation	TGAI	B,D,G	No		No[11/]	
72-7 Simulated or actual Field Testing - Aquatic Organism	TEP	B,D,G	No		Reserved[12/]	
Sec. 158.540 Plant Protection						
121-1 Target Area Phytotoxicity	TEP	B,D,G	No		No[5/]	

Table A
Generic Data Requirements for Resmethrin (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Sec. 158.540 -Wildlife and Aquatic Organisms						
Non-Target Area Phytotoxicity						
Tier I						
122-1 Seed Germination/ Seedling Emergence	TGAI	B,D,G	No		Yes[13]/	9 months
122-1 Vegetative Vigor	TGAI	B,D,G	No		Yes[13]/	9 months
122-2 Aquatic Plant Growth	TGAI	B,D,G	No		Yes[14]/	9 months
Tier II						
123-1 Seed Germination/ Seedling Emergence	TGAI	B,D,G	No		Reserved[15]/	
123-1 Vegetative Vigor	TGAI	B,D,G	No		Reserved[15]/	
123-2 Aquatic Plant Growth	TGAI	B,D,G	No		Reserved[15]/	
Tier III						
124-1 Terrestrial Field	TEP	B,D,G	No		No[5]/	
124-2 Aquatic Field	TEP	B,D,G	No		No[5]/	

Table A
Generic Data Requirements for Resmethrin (cont'd)

1/ Required to support the manufacturing use product that is reformulated into end use products.

2/ Required for all registrations with outdoor uses.

3/ The wild mammal test is not presently a requirement.

4/ Avian reproduction studies on bobwhite and mallard are required for technical Resmethrin because the mosquito use would subject birds to repeated exposure during the breeding season.

5/ Not currently a requirement.

6/ Tests using the soluble concentrate liquid, either 4%, 1.51 lb/gal, or 3.34 lb/gal for mosquito abatement are required to support the mosquito and other pest control uses at aquatic sites.

7/ Acute aquatic toxicity studies on aquatic invertebrates using the formulated product may be required when the product will be introduced directly into water, or when the maximum expected environmental concentration (MEEC) or estimated environmental concentration (EEC) exceeds the LC_{50} of the technical material. The presently registered uses for mosquito abatement include direct application to shorelines, beaches, tidal marshes, marsh lands, marshy areas, stagnant pools, and swamps. Also, the lowest labeled application rate for mosquito abatement results in an EEC greater than the LC_{50} for fish--the only aquatic organism with toxicity data on file.

Table A
Generic Data Requirements for Resmethrin (cont'd)

8/ Acute toxicity studies of the technical grade material are required for hazard evaluation, because of existing registration for mosquito control on and adjacent to marine and estuarine sites.

9/ Acute toxicity of soluble concentrate liquid, either 4%, 1.51 lb/gal, or 3.34 lb/gal registered for mosquito abatement are required for hazard evaluation because of existing registration for mosquito control on and adjacent to marine and estuarine sites.

10/ Chronic toxicity studies using marine/estuarine fish and invertebrates will be reserved pending the outcome of the lower tiered tests on marine/estuarine species, the freshwater early life stage, and the 21 day Daphnid life-cycle toxicity study.

11/ Deferred to Environmental Fate requirements.

12/ Testing of the soluble concentrate liquid, either 4%, 1.51 lb/gal, or 3.34 lb/gal for mosquito abatement are reserved pending the results of acute testing.

13/ All Tier I data on Nontarget Area Phytotoxicity are required for pesticides used in forest and natural grasslands.

14/ Aquatic Plant Growth data are required as special testing (Section 70-1) for the mosquito abatement use because that use involves application of resmethrin to aquatic habitats.

15/ Reserved pending results of Tier I studies.

Table A
Generic Data Requirements for Resmethrin

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Sec. 158.590 Nontarget Insects						
NONTARGET INSECT TESTING - POLLINATORS						
141-1 - Honey Bee Acute Contact LD50	TGAI	B	Yes	00142655	No	
141-2 - Honey Bee - Toxicity Residues on Foliage	TEP	B	No		Yes[1/]	15 months
141-4 - Honey Bee Subacute Feeding Study	Reserved[2/]					
141-5 - Field Testing for pollinators	TEP	B	No		No[3/]	
NONTARGET INSECT TESTING - AQUATIC INSECTS						
142-1 - Acute Toxicity to Aquatic Insects	Reserved[4/]					
142-2 - Aquatic Insect Life Cycle Study	Reserved[4/]					
142-3 - Simulated or Actual Field Testing for Aquatic Insects	Reserved[4/]					

Table A
Generic Data Requirements for Resmethrin

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
NONTARGET INSECT TESTING : PREDATORS AND PARASITES						
143-1	Reserved 4/					
through 143-3						
¶158.590 - Nontarget Insects Footnotes						

1/ As data from acute contact test indicate high toxicity, residual toxicity data are required.

2/ Reserved pending development of test methodology.

3/ Data reviewed to date do not indicate a need for field testing.

4/ Reserved pending decision whether the data requirement should be established.

TABLE B. GENERIC DATA REQUIREMENTS FOR RESMETHRIN MANUFACTURING-USE PRODUCTS.

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?[2]	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
158.190 Product Chemistry					
Product Identity and Composition					
61-1. Product Identity and Disclosure of Ingredients	MP	No	N/A	Yes[3]	9 months
61-2. Description of Beginning Materials and Manufacturing Process	MP	No	N/A	Yes[4]	9 months
61-3. Discussion of Formation of Impurities	MP	No	N/A	Yes[5]	9 months
Analysis and Certification of Product Ingredients					
62-1. Preliminary Analysis of Product Samples	MP	No	N/A	Yes[6]	12 months
62-2. Certification of Ingredient Limits	MP	No	N/A	Yes[7]	12 months
62-3. Analytical Methods to Verify Certified Limits	MP	No	N/A	Yes[8]	12 months
Physical and Chemical Characteristics					
63-2. Color	MP	No	N/A	Yes[9]	9 months
63-3. Physical State	MP	No	N/A	Yes[9]	9 months
63-4. Odor	MP	No	N/A	Yes[9]	9 months
63-7. Density, Bulk Density or Specific Gravity	MP	No	N/A	Yes[9]	9 months
63-12. pH	MP	No	N/A	Yes[9,10]	9 months
62-14. Oxidizing or Reducing Action	MP	No	N/A	Yes[9]	9 months
62-15. Flammability	MP	No	N/A	Yes[9,11]	9 months
63-16. Explodability	MP	No	N/A	Yes[9,12]	9 months
63-17. Storage Stability	MP	No	N/A	Yes[9]	15 months
63-18. Viscosity	MP	No	N/A	Yes[9,13]	9 months

(Continued, footnotes follow).

TABLE B. (Continued).

Data Requirement	Test Substance[1]	Does EPA have data to satisfy this requirement?[2]	Bibliographic Citation[2]	Must additional data be submitted under FIFRA Sec. 3(c)(2)(B)?	Time Frame For Data Submission
63-19. Miscibility	MP	No	N/A	Yes[9,14]	9 months
63-20. Corrosion Characteristics	MP	No	N/A	Yes[9]	15 months
Other Requirements:					
64-1. Submittal of Samples	N/A	N/A	N/A	No	

1. MP = manufacturing-use product. Since all MP are technical grade active ingredients, generic data required by Table A will suffice to meet the requirements of Table B.

2. Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

3. The product name, chemical name (Chemical Abstracts Index of Nomenclature or other well defined name), nominal concentration, certified limits, Chemical Abstracts Service (CAS) Registry Number, and purpose of each active ingredient and each intentionally added inert must be provided for each manufacturing-use product. The name and upper certified limit must also be provided for each impurity or group of impurities for which a certified limit is required. The information on ingredient limits must be submitted on EPA Form 8570-4 (Rev. 2/85).

4. Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

TABLE A. (Continued).

1. All currently registered technical products are also manufacturing-use products; therefore, additional data requirements pertaining to these products are listed in Table B.

2. TGAI = technical grade of the active ingredient. PAI = purified active ingredient.

3. Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

4. Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

5. A detailed discussion all impurities that are or may be present at $\geq$0.1%, including nitrosamines, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

6. Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete, detailed descriptions of the analytical methods used must be submitted along with statements of their precision and accuracy. Reports of preliminary analyses should include for each sample the identity of each ingredient for which analysis was conducted, the quantity that was found, and the mean and relative standard deviation of reported analytical results.

7. Data must be submitted on physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D. See Table B for additional requirements for data on physicochemical characteristics of technical products that are also manufacturing-use products.

TABLE B. (Continued).

12. Data are required if the product contains any potentially explosive ingredients.

13. Data on viscosity are required if the product is a liquid.

14. Data on miscibility are required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Table B
Product Specific Data Requirements for Manufacturing Use Products Containing Resmenthrin

Section Data Requirement	Test For Data Substance	Patterns	Does EPA Have Data to Use Requirement?	Satisfy This Citation	Must Additional Data Be Submitted Bibliographic 3(c)(2)(B)?	Timeframe Under FIFRA Submission
§158.340 Toxicology						
81-1 - Acute Oral - Rat	MP	All	No		Yes[1/]	9 Months
81-2 - Acute Dermal	MP	All	No		Yes[1/]	9 months
81-3 - Acute Inhalation	MP	All	Yes	00158477	No	
81-4 - Eye Irritation	MP	All	Yes	00028466	No	
81-5 - Dermal Irritation	MP	All	Yes	00028466	No	
81-6 - Dermal Sensitization	MP	All	Yes	00158478	No	

1/ Acceptable data derived from acute toxicity tests conducted on the TGAI will satisfy this requirement.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely.
[40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement.
[40CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON.
[40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage is given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-9

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1]/, dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations to be Part of the Data Base Supporting
Registrations Under the Resmethrin Standard

MRID Citation

00025552 Schwartz, C.S.; Becci, P.J.; Parent, R.A.; et al. (1979) Report: Evaluation of the Neurotoxic Effects of SBP-1382 in Albino Rats--Phase 1: FDRL Study # 6067. Includes method dated Jul 2, 1979. (Unpublished study including letter dated Nov 28, 1979 from R.W. Fogleman to B.B. Brown and Maarten devries, received Dec 19, 1979 under 432-487; prepared by Food and Drug Research Laboratories, Inc., submitted by Penick Corp., Lyndhurst, N.J.; CDL:241501-B)

00025553 Cox, G.E.; Becci, P.J.; Parent, R.A.; et al. (1979) Supplementary Report for Evaluation of the Neurotoxic Effects of SBP-1382 in Albino Rats--Phase I: FDRL Study # 6362. (Unpublished study including letter dated Nov 28, 1979 from R.W. Fogleman to B.B. Brown and Maarten L. derVies, prepared by Food and Drug Research Laboratories, Inc., received Dec 19, 1979 under 432-487; submitted by Penick Corp., Lyndhurst, N.J.; CDL:241502-B)

00025554 Schwartz, C.S.; Becci, P.J.; Parent, R.A.; et al. (1979) Report: Evaluation of the Neurotoxic Effects of SBP-1382 in Albino Rats: Phase II: FDRL Study # 6068. (Unpublished study including letter dated Nov 28, 1979 from R.W. Fogleman to B.B. Brown and Maarten L. deVries, received Dec 19, 1979 under 432-487; prepared by Food and Drug Research Laboratories, Inc., submitted by Penick Corp., Lyndhurst, N.J.; CDL:241503-B)

00028453 Machi, R.A.; Kam, C.; Gallo, M.A.; et al. (1979) Teratologic Evaluation of SBP-1382 Technical in the Albino Rat: Snell Project # 2054-066. (Unpublished study received Jan 23, 1980 under 432-487; prepared by Booz, Allen & Hamilton, Inc., submitted by Penick Corp., Lyndhurst, N.J.; CDL:241765-A; 241766; 241768; 241769; 241770)

00028466 Weeks, M.H.; Leland, T.M.; Boldt, R.E.; et al. (1972) Toxicological Evaluation of Pyrethroid Insecticide (5-Benzyl-3-furyl) methyl-2,2-dimethyl-3-(2-methylpropenyl) cyclopropanecarboxylate (SBP-1382):. Edgewood Arsenal, Md.: U.S. Army Environmental Hygiene Agency. (Special study no. 51-127-71/72; also in unpublished submission received Jul 25, 1979 under 432-547; submitted by Penick Corp., Lyndhurst, N.J.; CDL:240934-A)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations to be Part of the Data Base Supporting
Registrations Under the Resmethrin Standard

MRID Citation

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V. FORMS APPENDICES

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

Attach separate page with a list of the data requirements your company agrees to satisfy.

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

Attach list of data requirements

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

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EPA Form 8580-6

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

OMB Approval N
2070-0
Expires 11/30/

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No._____ Date_____

Guidance Document for_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

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OMB Approval N
2070-0
Expires 11/30/

PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No._____ Date_____

Guidance Document for_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	I am complying with data requirements by Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
Subpart C PRODUCT CHEMISTRY (cont'd)					
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization.				
81-7	Acute Delayed neurotoxicity, hen				

EPA Form 8580-4 (cont'd)

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OMB Approval No. 2070-0
Expiration Date 11/30/8

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number:_____

Registrant's Name and Address: _____

_____

As an authorized representative of the registrant of the product identified above certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _____ concerning a requirement for submission of "generic" data on the act: ingredient _____ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, desp: our lack of intent to submit the generic data in question, on the grounds that the prod contains the active ingredient solely as the result of the incorporation into the prod of another product which contains that active ingredient, which is registered under FI Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula (CSF) for the above-identif: product is attached to this statement. That formula statement indicates, by company nar registration number, and product name, the source of the subject active ingredient in firm's product, or

The CSF dated_____ on file with EPA is complete, current and accurate a contains the information requested on the current CSF Form 8570-4. The registe source(s) of the above named active ingredient in my product(s) is/are _____ and their registration number(s) is/are _____.

My firm will apply for an amendment to the registration prior to changing the sour of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion this Statement is no longer true, or if my firm fails to comply with the undertakings ma in this Statement, my firm's product's registration may be suspended under FIFRA Secti 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for t product, my firm relies on the efforts of other persons to provide the Agency with t required generic data. If the registrant(s) who have committed to generate and submit t required data fail to take appropriate steps to meet requirements or are no longer compliance with this Notice's data requirements, the Agency will consider that both th and my firm are not in compliance and will normally initiate proceedings to suspend t registrations of my firm's product(s) and their product(s), unless my firm commits submit and submits the required data in the specified time frame. I understand that, such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative:_____
(Signature

Dated: _____ _____
(Typed)

EPA Form 8570-27

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